REMARKS

Claims 23 – 40 have been canceled without prejudice or disclaimer of the subject matter thereof.

Claims 18 and 54 have been canceled by the subject amendment without prejudice or disclaimer of the subject matter thereof.

Claims 14 - 15, 19, 51 - 52, 55 and 59 - 64 have been amended.

Claims 1 – 17, 19 - 22, 41 – 53 and 55 - 64 are present in the subject application, with claims 1 – 13, 17, 20 – 22, 41 – 50, 53 and 56 – 58 being withdrawn from consideration due to a restriction requirement.

Applicants acknowledge the courtesies extended by Examiner Bockelman during a recent telephone Interview. During the telephone discussion, proposed claims were discussed. The Examiner indicated that incorporating features related to a medical solution container and medical fluid line may further distinguish the claims from the cited art (e.g., U.S. Patent Nos. 1,479,451 (Buckstein), 4,009,615 (Lester), 4,121,574 (Lester), and 5,829,880 (Diedrich), FR 2711393 and DE 3709122). Further, the Examiner indicated that features related to the temperature sensor providing an electrical temperature signal should overcome the cited Buckstein patent. In addition, the Examiner indicated that a response should be submitted for consideration of the issues and that the Examiner would contact Applicants' representative for further discussions, if necessary.

In the Office Action dated September 14, 2004, the Examiner has acknowledged the election by Applicants in response to a restriction requirement, has rejected claims 14, 18, 19, 51, 54 and 55 under 35 U.S.C. §102(b), and has rejected claims 14 - 16, 18, 19, 51 - 52, 54, 55 and

59 - 64 under 35 U.S.C. §103(a). Favorable reconsideration of the subject application is respectfully requested in view of the following remarks.

The Examiner has rejected claims 14, 18, 19, 51, 54 and 55 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No 5,829,880 (Diedrich), FR 2711393 or DE3709122. The Examiner has further rejected claims 15 - 16, 52 and 59 - 64 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No 5,829,880 (Diedrich), FR 2711393 or DE3709122. Since claims 18 and 54 have been canceled by the subject amendment, the rejection with respect to these canceled claims is considered moot. The Examiner takes the position that each of the references shows a temperature sensor in a T-tube with a cover and securing means with some type of recess for securing the probe in the T-tube. The Examiner further asserts that it would have been conventional to include electronic displays and a printer or recording means.

In order to expedite prosecution of the subject application, independent claims 14 and 51 have been amended to recite the features of: a medical solution container containing a sterile medical solution; a fluid line coupled to the medical solution container to receive the sterile medical solution; the fitting or connector means including a thermally conductive receptacle or thermal contact means including an open proximal end and a closed distal end to directly contact and conduct thermal energy from the sterile medical solution flowing within the passage or flow means; and a temperature sensor or temperature sensing means removably received within the open proximal end to generate an electrical temperature signal indicating the measured solution temperature. Claims 15, 19, 52, 55 and 59 - 64 have been amended for consistency with their amended parent claims.

This rejection is respectfully traversed since the Diedrich, French and German patent documents do not, disclose, teach or suggest each of the above features recited in the claims. Rather, the Diedrich patent discloses a media conducting device including a media conducting pipe with a lateral exit on which is arranged a group of sensors. This group includes a sensor housing with an electric temperature sensor with two contact pins projecting from the sensor housing (e.g., See Abstract). The media conducting device is especially for use in a motor vehicle air conditioning system to measure the temperature of flowing media in that system and to use the measured result for controlling the system (e.g., See Column 1, lines 1 - 5). Accordingly, the Diedrich patent does not disclose, teach or suggest a medical solution container containing a sterile medical solution and a fluid line coupled to the medical solution container to receive the sterile medical solution as recited in the claims.

The French patent document discloses a system for temperature tapping, especially on a plastic pipe, including a casing containing a fluid, a temperature sensor designed to measure temperature of the fluid, in which the casing has an opening through which a sensitive element of the temperature sensor penetrates the casing and means for fastening the temperature sensor onto the external wall of the casing. The system further includes a cap sealed against the fluid and independent of the temperature sensor placed in the casing to envelop the sensitive element of the temperature sensor completely and therefore allow the latter to be removed without the risk of the fluid leaking. The system is preferably used with motor vehicle coolant (e.g., See Abstract). Accordingly, the French patent document does not disclose, teach or suggest a medical solution container containing a sterile medical solution and a fluid line coupled to the medical solution container to receive the sterile medical solution as recited in the claims.

The German patent document discloses a temperature-measuring device allowing non-sterile temperature sensors to be used in a sterile respiratory system to precisely measure respiratory gas temperatures without contaminating the system. A translation of the German patent document is enclosed for the Examiner's convenience and review. In particular, the German patent document discloses a Y-component made of plastic and including a protective temperature measuring sleeve. The Y-component is connected to an accordion respiration tube, where the sleeve receives a temperature sensor to measure respiratory gas temperature. Accordingly, the German patent document does not disclose, teach or suggest a medical solution container containing a sterile medical solution and a fluid line coupled to the medical solution container to receive the sterile medical solution as recited in the claims.

Since the Diedrich, French and German patent documents do not disclose, teach or suggest the features recited in independent claims 14 and 51 as discussed above, these claims are considered to overcome those cited patent documents.

Claims 15, 16, 19, 52, 55 and 59 - 64 depend, either directly or indirectly, from independent claims 14 or 51 and, therefore, include all the limitations of their parent claims. These claims are considered to overcome the cited patent documents for substantially the same reasons discussed above in relation to their parent claims and for further limitations recited in the dependent claims.

The Examiner has rejected claims 14 and 51 under 35 U.S.C. §102(b)/103(a) as being anticipated by or, in the alternative, unpatentable over U.S. Patent No. 1,479,451 (Buckstein), alone or in combination with U.S. Patent No. 4,121,574 (Lester) or U.S. Patent No. 4,009,615 (Ruhl). The Examiner has further rejected claims 15 - 16, 52 and 59 - 64 under 35 U.S.C.

§103(a) as being unpatentable over U.S. Patent No. 1,479,451 (Buckstein) in view of U.S. Patent No. 4,121,574 (Lester) and/or U.S. Patent No. 4,009,615 (Ruhl). The Examiner takes the position with respect to independent claims 14 and 51 that the Buckstein patent teaches an in line member for measuring temperature in an IV system with a fitting with first and second connectors with a flow path in the housing and a connection port and a temperature sensor in the form of a thermometer which generates a visible signal that can facilitate electronic display. The Examiner alternatively asserts that it would have been obvious to replace the thermometer with a digital thermometer to attain the claimed invention.

This rejection is respectfully traversed. Initially, claims 14 and 51 recite the features of: the fitting or connector means including a thermally conductive receptacle or thermal contact means including an open proximal end and a closed distal end to directly contact and conduct thermal energy from the sterile medical solution flowing within the passage or flow means; and a temperature sensor or temperature sensing means removably received within the open proximal end to generate an electrical temperature signal indicating the measured solution temperature as discussed above.

The Buckstein patent does not disclose, teach or suggest these features. Rather, the Buckstein patent discloses a fluid administering device including a vacuum container with a vacuum bottle or Dewar flask filler. The container is sustained in an inverted position with delivery therefrom being effected through an outlet tube. The container carries measuring accessory means for indicating the volume and temperature of the delivered fluid. For ascertaining the temperature, a thermometer, preferably encased, is removably retained in a socket through which fluid is delivered in contact with the thermometer bulb on its way to the

outlet (e.g., See Page 1, lines 33 to Column 63). The glass tube of the thermometer is encased in a metal shell for protection. The metal tube extends above a metallic closure plug removably threaded into the socket, where the plug is packed by a rubberized fabric washer to prevent leak (e.g., See Page 2, lines 88 - 98). Thus, the Buckstein patent discloses a thermometer encased in a metal shell and removably inserted through a socket plug to contact and measure fluid temperature, as opposed to a thermally conductive receptacle or thermal contact means including an open proximal end and a closed distal end to directly contact and conduct thermal energy from the sterile medical solution within the passage or flow means, where the receptacle or thermal contact means forms a fluid tight seal. Further, the thermometer of the Buckstein patent is read by a user, as opposed to generating an electrical signal as recited in the claims.

The Ruhl and Lester patents do not compensate for the deficiencies of the Buckstein patent and similarly do not disclose, teach or suggest these features. Rather, the Lester patent discloses a method and apparatus for displaying the vital signs of a patient wearing an alphanumeric identification bracelet and including a temperature sensing probe for making body contact with the patient, a portable data-gathering acquisition unit and electronic anticipation circuitry disposed in the acquisition unit and coupled to the probe for sensing the change in patient temperature and predicting the stabilized temperature of the patient (e.g., See Abstract). The Ruhl patent discloses a self-contained electronic digital thermometer in the form of an elongated probe having a temperature transducing thermistor at the front end and an electronic digital display at a rear end (e.g., See Abstract).

Since the Buckstein, Lester and Ruhl patents do not disclose, teach or suggest, either alone or in combination, the features recited in independent claims 14 and 51 as discussed above, these claims are considered to be in condition for allowance.

Claims 15 - 16, 52 and 59 - 64 depend, either directly or indirectly, from independent claims 14 or 51 and, therefore, include all the limitations of their parent claims. These claims are considered to be in condition for allowance for substantially the same reasons discussed above in relation to their parent claims and for further limitations recited in the dependent claims.

The Examiner has rejected claims 18 - 19 and 54 - 55 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 1,479,451 (Buckstein) in view of U.S. Patent No. 4,121,574 (Lester) and/or U.S. Patent No. 4,009,615 (Ruhl) and further in view of FR 2711393 or DE3709122. Since claims 18 and 54 have been canceled by the subject amendment, the rejection with respect to these canceled claims is considered moot. The Examiner takes the position that the claimed subject matter differs from the combination of the Buckstein, Lester and Ruhl patents by reciting a cover/receptacle and a securing means with a recess for interfacing with the fluid. The Examiner further asserts that the French patent document teaches a securing means with a recess cavity, while the German patent document teaches a similar embodiment with a cover, and that it would have been obvious to provide Buckstein, disclosing a recess in the form of a thread for receiving the probe, with a digital thermometer to attain the claimed invention.

This rejection is respectfully traversed. Initially, claims 19 and 55 depend, either directly or indirectly, from independent claims 14 or 51 and, therefore include all the limitations of their parent claims. As discussed above, the combination of the Buckstein, Lester and Ruhl patents

does not disclose, teach or suggest the features of a thermally conductive receptacle or thermal contact means including an open proximal end and a closed distal end to directly contact and conduct thermal energy from the sterile medical solution flowing within the passage or flow means and a temperature sensor or temperature sensing means removably received within the open proximal end to generate an electrical temperature signal as recited in the claims.

The French and German patent documents do not compensate for the deficiencies of the combination of the Buckstein, Lester and Ruhl patents. As discussed above, these documents pertain to measuring air conditioning system media for motor vehicles and motor vehicle coolants and do not disclose, teach or suggest measuring temperature of sterile medical solutions via the fitting or connector means of a fluid line as recited in the claims.

Since the Buckstein, Lester and Ruhl patents and the French and German patent documents do not disclose, teach or suggest, either alone or in combination, the features recited in claims 19 and 55 as discussed above, these claims are considered to be in condition for allowance.

In view of the above, none of the cited patent documents disclose, teach or suggest measuring temperature of sterile medical solutions via the fitting or connector means of a fluid line as recited in the claims. In addition, there is no reason or motivation to combine the Buckstein, Lester and Ruhl patents and the French and German patent documents to attain the claimed invention. Initially, the Buckstein patent is directed toward a fluid administering apparatus employing a thermometer encased in a metal shell for sterilization and protection. Although the Lester and Ruhl patents disclose electronic and/or digital thermometers, these types of thermometers generally would require wires extending beyond the sterile metal shell to

transmit signals and/or opening of the shell for manual manipulation of control buttons/switches by a user for operation, thereby contaminating the sterile field. Further, the French and German patent documents pertain to measuring air conditioning system media for motor vehicles and motor vehicle coolants and provide no disclosure, teaching or suggestion of measuring temperature of sterile medical solutions. Accordingly, there is no reason or motivation to combine the documents, and the proposed combinations of patent documents discussed above do not render the claimed invention obvious.

The application, having been shown to overcome issues raised in the Office Action, is considered to be in condition for allowance and a Notice of Allowance is earnestly solicited.

Respectfully submitted,

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Request for examination has been filed in accordance with § 44 of the Patent Law.

(54) Temperature Measuring Device for the Sterile, Precise Measurement of Respiratory Gas Temperature in Respiration Tube Systems Using Non-Sterile Sterilizable Sensors

A temperature-measuring device is described, which allows non-sterile temperature sensors to be used in a sterile respiration system to precisely measure respiratory gas temperatures without contaminating the system.

Patent Claims

1. Temperature measuring device for the sterile, precise measurement of respiratory gas temperature in respiration tube systems using non-sterile, sterilizable sensors, **characterized in that** it is comprised of a protective temperature measuring sleeve which is made of highly thermally conductive material, e.g. metal, and is hermetically sealed, e.g. is inserted into a Y-, T-component or a ventilation port made of plastic material, and is inserted in such a way that the greatest possible portion of the sleeve lies inside the lumen and thus within the respiratory gas flow, in order to absorb the greatest possible quantity of heat, and in that the loss of heat through the sleeve to the surrounding plastic material and the surrounding air is minimized, and in that a non-sterile sensor which functions via electrical-electronic or some other known principle fits and is inserted into the sleeve so that there results the greatest possible, close contact with an optimal heat transfer.
2. Temperature measuring device for the sterile, precise measurement of respiratory gas temperature in respiration tube systems using non-sterile/sterilizable sensors pursuant to Claim 1, characterized in that the protective temperature-measuring sleeve is designed in such a way that its lumen tapers conically at a shallow angle, corresponding to the also conically shaped temperature sensing stylus of the temperature sensor.
3. Temperature measuring device for the sterile, precise measurement of respiratory gas temperature in respiration tube systems using non-sterile/sterilizable sensors pursuant to Claims 1 and 2, characterized in that the measuring sleeve or the sensing stylus of the temperature sensor is provided with a thermal compound, e.g. one with a silicone base.
4. Temperature measuring device for the sterile, precise measurement of respiratory gas temperature in respiration tube systems using non-sterile/sterilizable sensors pursuant to Claims 1 and 2, characterized in that the larger-diameter section of the protective temperature measurement sleeve which is inserted into the plastic material has a thinner wall thickness than the section that lies inside the lumen (respiratory gas flow).
5. Temperature measuring device for the sterile, precise measurement of respiratory gas temperature in respiration tube systems using non-sterile/sterilizable sensors pursuant to Claims 1 - 4, characterized in that the section of the protective temperature measuring sleeve that is inserted into the plastic material reaches only to the surface of this plastic component.
6. Temperature measuring device for the sterile, precise measurement of respiratory gas temperature in respiration tube systems using non-sterile/sterilizable sensors pursuant to Claims 1 - 5, characterized in that even with the firm, manual insertion of the temperature sensing stylus into the section of the protective temperature measuring sleeve which projects into the respiratory gas flow, an air-filled, thermally insulating gap still exists between the section of the protective temperature measuring sleeve that has been inserted into the plastic material and the clamp mounting cone of the temperature sensor housing.

7. Temperature measuring device for the sterile, precise measurement of respiratory

gas temperature in respiration tube systems using non-sterile/sterilizable sensors pursuant to Claims 1 - 6, characterized in that the outer surface of the temperature sensing stylus or the inner surface of the protective temperature sleeve is equipped with a groove along the entire length of its longitudinal axis.

Description

The invention relates to a temperature-measuring device pursuant to the preamble of Patent Claim 1.

With artificial respiration, it is necessary to establish precise respiratory temperatures within the range of 34-37° C with 80-100% relative moisture, in order to be able to properly suction off the patient's tracheo-bronchial mucous and to prevent complications, such as tracheal tubes being clogged with viscous phlegm or thermal damage to the bronchial mucosa with the associated risk of life-threatening hemorrhaging. For that reason, thermometers, or in recent years increasingly precise electrical-electronic sensors, are employed in the respiration tube systems, in order to measure the respiratory gas temperature as close to the patient as possible. However, because under artificial respiration the inside of the respiration tube system comes into direct contact with the patient's bronchial system, great care must be taken to keep the system sterile, in order to prevent life-threatening pneumonia. For this purpose electrical-electronic temperature sensors are available on the market that can be heat sterilized along with their power cords and plugs. This requires a very time-consuming and costly construction. But many other sensors available on the market cannot be heat sterilized, and instead can be rendered bacteria-poor or bacteria-free only via disinfection processes or vapor sterilization. Today these processes are considered dangerous for the patient and thus are eliminated whenever possible.

The object of the invention described below is to provide a way in which a precise temperature measurement of respiratory gases can be taken close to the patient under sterile conditions within the tube system, without requiring costly steam-sterilizable or disinfectable sensors.

The object is attained with the features contained in the characterizing portion of Claim 1. The expensive, conventional temperature sensors that can be steam sterilized and are costly in terms of their construction are herewith replaced by an easily manufactured temperature sensor that is inserted into a protective temperature measuring sleeve made of metal which is integrated into a Y-, T-component or into the ventilation port of the sterile respiratory system, and thus need not be sterilized.

Further advantageous embodiments of the invention are disclosed in the Claims 2-6.

Technical Description of one Exemplary Embodiment

Fig. 1 shows a perspective, schematic view of the Y-component made of plastic material and connected to an accordion respiration tube (1), with an integrated

temperature measuring device (2) into which a temperature sensor (3) with its connecting cable (13) is inserted.

Fig. 2 shows the entire temperature-measuring device as shown in Fig. 1 in a longitudinal section (I...I) in detail.

The non-sterile temperature sensor (3) is inserted with its clamp-mounting cone (4) and its temperature sensor (5) into the protective temperature measuring sleeve (Component I, 6 Component II, 7), with said sensor extending into the lumen of the Y-component (10) up close to its wall (11), so that the stream of warm respiratory gas (12) indicated by the arrow, flows around it. As can be seen from Fig. 2, the conical temperature stylus with the sensor element (5) is pressed into the conical protective temperature-measuring sleeve (Component II, 7) such that there is no air gap between the stylus and the protective sleeve. In contrast, however, between the clamping-mounting cone (4) and the protective temperature-measuring sleeve (thin-walled section I, 6), which is inserted into the thick-walled plastic material of the Y-component (9) such that it is airtight, a cylindrical air gap (8) is present.

Functional Description:

The non-sterile temperature sensor (3) is manually inserted under a specific level of pressure into the protective temperature-measuring sleeve (6, 7) that is integrated into the Y-component (2). Because the temperature stylus (5) is conical, just like the portion of the protective temperature-measuring sleeve (component II, 7) in which it fits, the closest possible contact between the temperature stylus and the protective sleeve is achieved, which is necessary for an undisrupted, optimal transfer of heat (no heat insulation from air pockets). If the sensor does not fit with the greatest degree of precision, adequate heat transfer can still be achieved by preventing an air pocket with the supplementary use of a thermal compound (e.g. with a silicone base). The clamping-mounting cone (4) of the temperature sensor then serves only as a mechanical guide, and no longer as a clamp in the protective temperature-measuring sleeve (Component I, 6) of the Y-component. The air gap (8) that is constructively possible between the cone (4) and the measuring sleeve (6) then creates a heat-insulating air pocket between the sensor housing and the cone (3, 4) and the measuring sleeve (6). The thick walls of the plastic Y-component (9) also provide additional thermal insulation. Because Component II (7) of the protective temperature-measuring sleeve is exposed over large areas to the warm respiratory gas flow (12), it is also ensured, that a larger quantity of heat is also absorbed, which is achieved not only via the above-mentioned thermal insulation measures, but also via poorer heat conduction as a result of a thinning of material in the transition from Component II (7) to Component I (6) of the protective temperature-measuring sleeve.

All of the above-described measures make is possible to measure respiratory gas temperatures with a high degree of precision using non-sterile sensors within a sterile system.